4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-E-0296]

Determination of Regulatory Review Period for Purposes of Patent Extension; COFLEX INTERLAMINAR TECHNOLOGY

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for COFLEX INTERLAMINAR TECHNOLOGY and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patents and Trademarks Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESSES: Submit electronic comments to http://www.regulations.gov. Submit written petitions (two copies are required) and written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit petitions electronically to http://www.regulations.gov at Docket No. FDA-2013-S-0610.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Management, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Bldg., rm. 3180, Silver Spring, MD 20993-0002, 301-796-7900.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device COFLEX INTERLAMINAR TECHNOLOGY. COFLEX INTERLAMINAR TECHNOLOGY is indicated for use in one- or two-level lumbar stenosis from L1-L5 in skeletally mature patients with at least moderate impairment in function, who experience relief in flexion from their symptoms of leg/buttocks/groin pain, with or without back pain, and who have undergone at least 6 months of non-operative treatment. Subsequent to this approval, USPTO received a patent term restoration application for COFLEX INTERLAMINAR TECHNOLOGY (U.S. Patent No. 5,645,599) from

Paradigm Spine, LLC, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated December 24, 2013, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of COFLEX INTERLAMINAR TECHNOLOGY represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that the FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for COFLEX INTERLAMINAR TECHNOLOGY is 2,382 days. Of this time, 1,787 days occurred during the testing phase of the regulatory review period, while 595 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C act) (21 U.S.C. 360j(g)) involving this device became effective: April 12, 2006. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the FD&C act for human tests to begin became effective on March 10, 2006. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on April 12, 2006, which represents the IDE effective date.

2. The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e): March 3, 2011. The applicant claims March 4, 2011, as the date the premarket approval application (PMA) for COFLEX INTERLAMINAR TECHNOLOGY (PMA P110008) was initially submitted. However, FDA records indicate that PMA P110008 was submitted on March 3, 2011.

3. The date the application was approved: October 17, 2012. FDA has verified the applicant's claim that PMA P110008 was approved on October 17, 2012.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,503 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments and ask for a redetermination by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by [INSERT DATE 180 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) electronic or written comments and written or electronic petitions. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to http://www.regulations.gov, Docket No. FDA-2013-S-0610.

Comments and petitions that have not been made publicly available on http://www.regulations.gov may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 1, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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